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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TXR# 0053484

DATE: June 27, 2005

MEMORANDUM:

SUBJECT: **MESOTRIONE** - Request for waiver of EPA requirement for a 28-day inhalation study (MRID 46562908)

PC Code: 122990
DP Barcode #: D318272

From: Robert J. Mitkus
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ACTION REQUESTED: On June 2, 2005, Syngenta Crop Protection, Inc. submitted to the Registration Division (RD) a waiver request (MRID 46562908) for a 28-day inhalation study, which was required under conditional registration of Mesotrione for field corn. The Health Effects Division (HED) was asked to review the waiver request.

CONCLUSIONS:

The Health Effects Division (HED) is granting the waiver request for a 28-day inhalation study. A 28-day inhalation study is not required as a condition for registration of mesotrione for field corn.

RATIONALE:

Current HED standard practice is to review several key factors regarding a compound, relative to the requirement for an inhalation study. Some of these factors include the following: 1) acute inhalation toxicity category; 2) the volatility of a compound; and 3) estimated inhalation Margins of Exposure (MOEs).

The Health Effects Division Risk Assessment Review Committee (RARC) identified mesotrione in acute inhalation toxicity category IV. The vapor pressure of mesotrione is 5.7×10^{-6} Pascals at 20°C. Because the vapor pressure is $<1 \times 10^{-1}$ Pascals at 20-30°C, mesotrione is considered essentially non-volatile for outdoor uses.

The **inhalation** Margin of Exposure is 17361 for mixer/loaders (the sub-population of workers with the highest surrogate exposures) using short-term open pour of liquids in support of aerial operations on **field corn**. The inhalation MOE was derived according to the following formula: Inhalation LOAEL ÷ Inhalation Average Daily Dose. The short-term MOE was calculated using the maximum exposure levels, application rates, and acres treated listed in Table 7.0 of the mesotrione risk assessment for field corn (Memo, S. Levy et al., D260267, 6-JUN-2001). There are no registered residential/non-occupational uses of mesotrione.

Since mesotrione is classified in acute inhalation toxicity category IV, the vapor pressure is low at 5.7×10^{-6} Pascals at 20°C, and the estimated inhalation MOE exceeds HED's level of concern, HED concludes that it is appropriate to waive the requirements of a 28-day inhalation study for conditional registration of mesotrione for the proposed use (field corn).